



Biotech Daily

Friday June 1, 2018

Daily news on ASX-listed biotechnology companies

- * MAY BDI-40 UP 3%, ASX200 0.5%, BIG CAPS 8% NBI 5%
- * TODAY: ASX DOWN, BIOTECH UP:
- FACTOR UP 6%; COMPUMEDICS DOWN 8%
- * DR BOREHAM'S CRUCIBLE: GENETIC SIGNATURES
- * CYNATA STEM CELLS 'EFFECTIVE FOR DIABETIC ULCERS IN MICE'
- * BENITEC RIGHTS RAISE \$6.2m OF HOPED-FOR \$17.4m; TOTAL \$8.8m
- * OPTISCAN CE MARK, DELIVERY DELAYS, DARREN LURIE ON \$1k/DAY
- * TPI 25% REMUNERATION REPORT 1st STRIKE
- * ONCOSIL PLEADS SCHULTZ TO ASX 34.5% QUERY
- * MMJ TAKES 13% OF BIEN FOR MARIJUANA FOOD, DRINK POWDER
- * PAUL, ELEANOR STEPHENS TAKE 8% OF RHINOMED
- * ROBERT PETERS TAKES 13% OF MEMPHASYS
- * IMAGION TO RELEASE 3.5m ASX ESCROW SHARES
- * BTC LOSES DIRECTOR BRUCE HANCOX

MARKET REPORT

The Australian stock market fell 0.36 percent on Friday June 1, 2018 with the ASX200 down 21.5 points to 5,990.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, eight fell, 13 traded unchanged and three were untraded. All three Big Caps were up.

Factor Therapeutics was the best, up 0.3 cents or 6.1 percent to 5.2 cents with 459,057 shares traded. Admedus, Airxpanders, Cochlear and Prescient climbed more than three percent; Actinogen, Ellex, Immutep and Orthocell rose more than two percent; Bionomics, Cynata, Nanosonics, Opthea and Sirtex were up more than one percent; with CSL, Medical Developments, Pro Medicus, Resmed and Starpharma up less than one percent.

The BDI-40 best for May, Compumedics, led the falls, retreating six cents or 8.3 percent to 66 cents with 636,800 shares traded. Impedimed lost 5.7 percent; Mesoblast fell 4.25 percent; Osprey and Volpara were down more than three percent; Uscom shed 2.9 percent; with Optiscan and Telix down by less than one percent.

[BIOTECH DAILY TOP 40 INDEX \(BDI-40\)](#)

May was good for Australian biotech with many stocks at 12-month highs, some at all-time highs, and both the collective Big Caps and the adjusted BDI-40 at their highest ever.

There were a number of small falls in the lower ranks as some companies that may have been over-valued sorted themselves out.

The Biotech Daily Top 40 Index (BDI-40) climbed 3.1 percent for the month, up 29.0 percent for the year to May 31, 2018 - in part reflecting significant falls by Mesoblast and Sirtex a year ago - while the ASX200 was up 0.5 percent for the month and 5.0 percent for the year.

The Nasdaq Biotechnology Index (NBI) was up 4.7 percent in May and 13.9 percent for the year (see charts below which include the Big Caps three-year chart for the first time).

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) improved 7.8 percent for the month and 42.5 percent for the year.

CSL was up 9.1 percent to \$84,079 million, Resmed improved 6.5 percent to \$19,296 million with Cochlear up 1.1 percent to \$11,288 million.

Twenty-one of the BDI-40 companies were up, of which five were up by more than 40 percent in the month and eight were up more than 20 percent. Eighteen fell, with eight down by more than 10 percent. One was unchanged.

Compumedics was the best, up 88.2 percent on yesterday's China deal to \$128 million, followed by Immutep up 53.4 percent to \$112 million, Oncosil (48.75%), Volpara (44.3%), Actinogen (43.75%), Prescient (38.1%), Factor Therapeutics (24.2%), Genetic Signatures (24.2%), Polynovo (17.9%), Orthocell (15.4%) and Nanosonics (10.4%).

Airxpanders led the falls for the second month in a row, down a further 42.9 percent to \$24 million from more than \$200 million just five months ago, followed by Reva (27.4%), LBT (17.9%), Admedus (15.5%), Medical Developments (15.4%) and Uscom (14.3%).

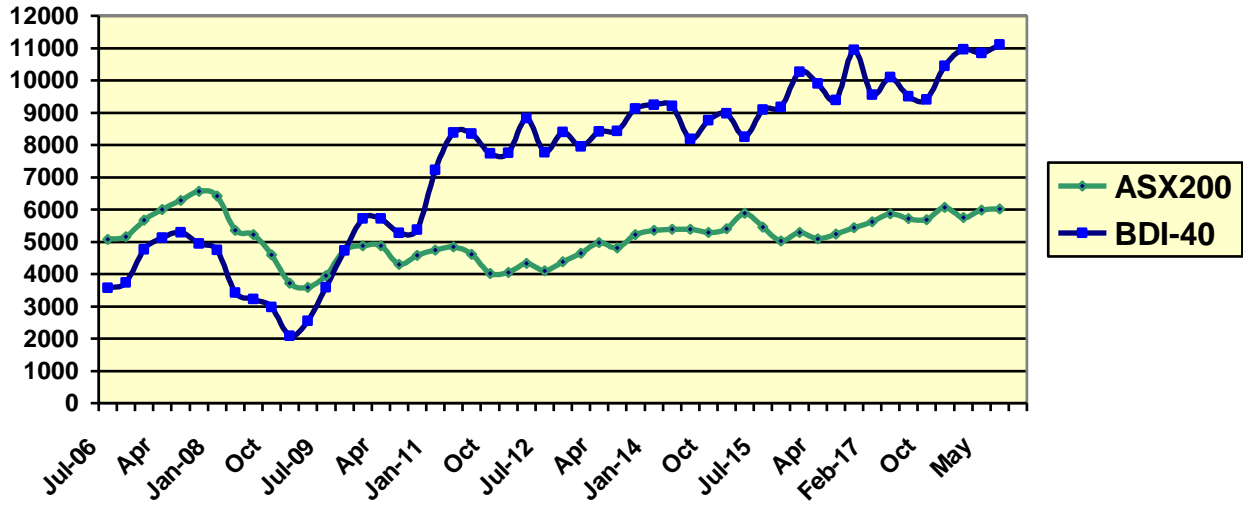
Outside the BDI-40, Invion, Nuheara, Patrys and Phosphagenics were all showing consistent improvement.

But over in Cannabis Corner, the buzz was starting to wear off the 16 pot-stocks, which fell a collective 9.9 percent, with all down except for Botanix up 47.0 percent to \$97 million and two that couldn't move.

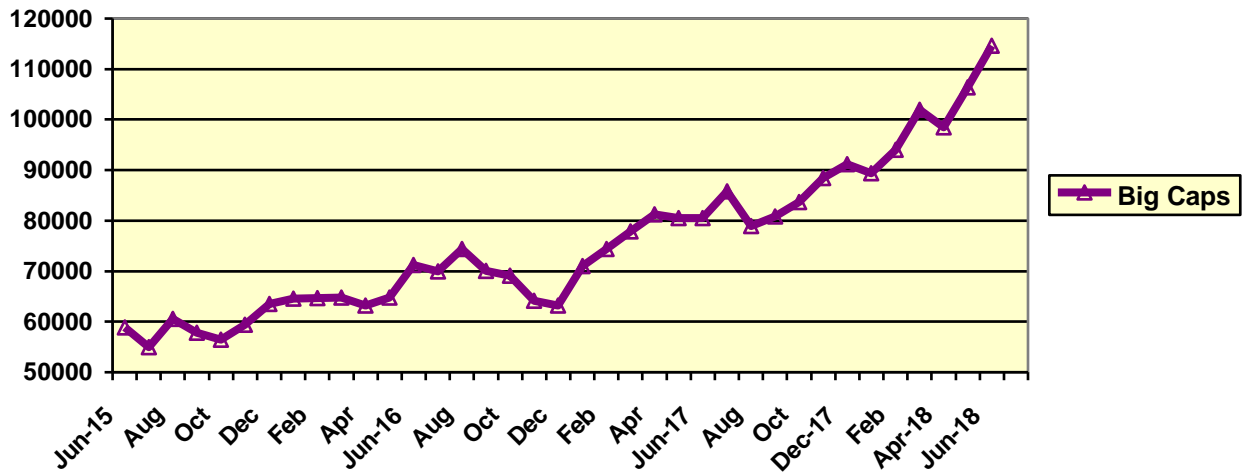
In the US, Redhill recovered 46.7 percent to \$201 million, Queensland's Protagonist slipped 16.0 percent to \$204 million and Vaxart (half Biota) yo-yoed up 93 percent to \$48 million.

While Biotech Daily is impressed with the Airxpanders post-mastectomy breast enhancement technology the company is struggling and will move to the Second 20, making room for Volpara which has shown consistent improvement through the year.

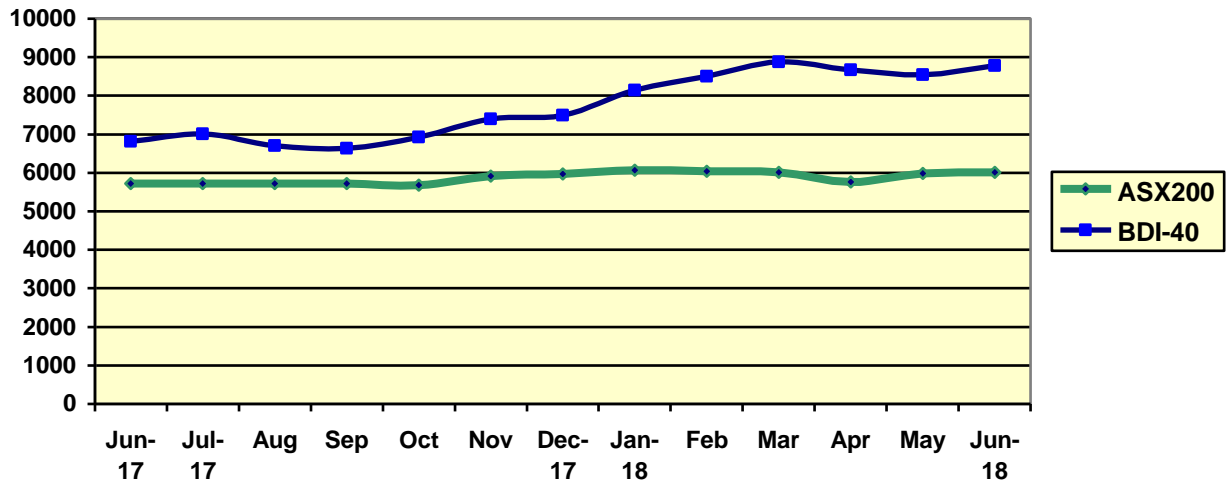
BDI-40 v ASX200 Jun 30, 2006 to May 31, 2018 - Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) May 31, 2015 – May 31, 2018



BDI-40 (\$m) v S&P ASX 200 – May 31, 2017 - May 31, 2018



DR BOREHAM'S CRUCIBLE: GENETIC SIGNATURES

By TIM BOREHAM

ASX code: GSS

Share price: 40 cents

Shares on issue: 103,926,937

Market cap: \$41.6 million

Chief executive officer: Dr John Melki

Board: Dr Nick Samaras (chairman), Phillip Isaacs, Dr John Melki, Michael Aicher, Dr Tony Radford.

Financials (March quarter): revenue \$714,000, cash receipts \$1.25 million, cash used \$1.1 million, cash on hand \$10.6 million, estimated current quarter cash burn \$2.3 million.

Identifiable major holders: Christopher Abbott (Asia Union Investments) 36.8%, Citi Nominees* 16.2%, John Melki 1.05%, estate of the late Ailsa Clare Grigg 0.94%, Capital Concerns (Logue family super fund) 0.93%, Doug Millar 0.91%.

* Denotes an offshore health fund.

We're sure the molecular diagnostics house doesn't gloat on the misfortunes of others, but last year's horror 'flu season was a ripper for the company.

In management's more measured parlance, Genetic Signatures (not to be confused with DNA tester now blockchain aspirant Genetic Technologies) benefited from last year's "particularly adverse domestic flu season".

Genetic Signatures' 3base testing technology targets conditions that require a faster and more accurate diagnosis, delivering just that by using a unique technique.

Sold under the Easyscreen brand, Genetic Signatures has five test kit variations and 12 in development.

The extant ones cover the killer 'flu, gastroenteric woes, flavivirus/alphavirus, antibiotic resistant bugs and - most importantly for some - sexually transmitted infections (STIs).

Flaviviruses are spread by mozzies and ticks and include zika and west Nile viruses.

The company is also trialling kits for meningitis.

Genetic Signatures' most advanced product, Easyscreen Enteric detects more than 20 tummy bugs. These include the dreaded norovirus, which has turned many a pleasant P&O cruise into a marathon maritime chunder-thon.

Influenza is among 14 nasties the company's respiratory test targets, but an important one.

"We are certainly gearing up to supply more tests for the upcoming 'flu season," Dr Melki says.

"After all, we make diagnostics to try to save lives."

Quicker, better diagnosis

The tests are based on the company's 3base proprietary technology which "optimizes DNA analysis by simplifying the natural sequences, resulting in faster and more accurate analysis".

3base takes the genetic information of the targeted organism and then changes the genetic sequence to make it easier to detect.

In essence, the test reduces the variables from one million to 60,000, with turnaround time for the client pathology laboratories reduced from five days to less than five hours.

"We can do what no-one else can," Dr Melki says.

"For example, we can look for 20 causes of gastro [enteritis] and do 200 tests at a time."

Genetic Signatures competes with other molecular diagnostics outfits, as well as the traditional agar plate testing.

The story to date

Genetic Signatures can date its ASX history to March 2015, when it debuted after raising \$7.5 million at 40 cents apiece.

The company was created in 2001, based on technology developed under the guidance of the late Dr Geoffrey Grigg.

And, yes, there has to be a CSIRO link: Dr Grigg worked for the esteemed public institution in the 1990s.

Dr Grigg also founded the listed Cambridge Antibody Technologies and Peptide, so if there were a Biotech Hall of Fame, Doc Grigg would have to be in it.

Dr Melki joined the company in 2003, having researched DNA and microarray technologies. For his efforts, the Doctor of Philosophy was awarded the Sydney University Peter Bancroft Prize in 2001.

Board member Dr Tony Radford is also a biotech old hand, having co-founded the tuberculosis diagnosis outfit Cellestis (acquired by Germany's Qiagen).

Dr Radford's outstanding discipline and impeccable grammar can be attributed to being taught by your columnist's late father, an English master who kept errant and students in line with the help of flying chalk.

Regulatory progress

Genetic Signatures government relations people have their clip boards full, given the company's busy slate of regulatory approval applications.

Genetic Signatures already has an approved product in Australia and Europe for enteric testing.

In April the Europeans approved its antibiotic resistance (superbug) testing kits and the local Therapeutic Goods Administration followed suit in mid-May.

The European enteric market alone is worth \$US86 million a year.

The company has applied for TGA and European approval for its respiratory, STI and flavivirus/alphavirus tests and is also seeking US approval for its enteric protozoan testing kit.

"We have now put nine products through CE Mark and TGA [regulatory procedures] so it's something we understand quite well," Dr Melki says.

The Australian market accounts for only 1.25 percent of the global molecular diagnostics market, which the company values at \$US7.6 billion, or thereabouts.

The company is also gaining favour in the Emerald Isle, which has just declared a superbug epidemic a national health emergency.

Ireland's CPE Reference Laboratory last month said it had tested the antibiotic kits and liked what it saw. The researchers then re-checked the results, to be sure, to be sure.

Sound financial diagnosis

Genetic Signatures' revenues have steadily increased from \$300,000 in 2012-'13 to \$2 million in 2016-'17 and \$1.43 million for the December half year (up 55 percent).

Dr Melki won't reveal the cost of the tests, but notes that they are consumable single-use items. He adds that customers can use their existing equipment to carry out the tests, so don't need a capital outlay.

"Our goal is to have the tests used in a routine way, so it has to be affordable and bring value to the lab," he says.

Genetic Signatures last raised \$14 million a year ago in a placement and share purchase plan, to support the regulatory approval process, but with cash of \$11 million it's not desperate to raise more.

Dr Boreham's (non-molecular) diagnosis:

One doesn't need a cutting-edge DNA detection kit to work out that Genetic Signatures has disappointed investors, despite the steady revenue growth.

Genetic shares peaked at 90 cents in January 2016 and sunk to a recent (February 18) low of 27.5 cents.

But revenues are heading the right way and will take off in a hockey-stick manner if the company wins the expected regulatory approvals. In fact, the shares enjoyed a nice leg-up after last month's TGA win.

The broader molecular diagnostics sector is well-competed and has also been subject to some big-ticket transactions.

In January this year, Qiagen acquired the like-minded private Spanish mob Stat-Dx for \$US191 million.

The blushing Genetic Signatures can boast a not-so-secret admirer in the guise of 38 percent shareholder Christopher Abbott.

The octogenarian Mr Abbott is best known as co-founder of the boutique investment house Maple Brown Abbott and a keen supporter of the biotech sector.

Mr Abbott was a shareholder on listing and has topped-up along the way and has never sold. That's loyalty.

Let's hope his enthusiasm is as contagious as the indications the company has targeted for testing.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. The last time he caught the 'flu, he didn't need a molecular test kit to diagnose it.

CYNATA THERAPEUTICS

Cynata says pre-clinical data shows its Cymerus mesenchymal stem cells are effective in treating diabetic ulcers in mice.

Cynata said that studies conducted by the Adelaide-based Cooperative Research Centre for Cell Therapy Manufacturing were designed to compare cells from various sources and showed that its Cymerus mesenchymal stem cells (MSCs) resulted in significantly faster wound healing than bone marrow-derived MSCs.

The company said that discussions with the Centre were underway regarding progressing Cymerus MSCs and the Centre's wound-dressing technology into a clinical trial in human patients with diabetic foot ulcers.

Cynata said that diabetic wounds were prevalent among the more than 400 million diabetics globally and a significant opportunity existed to improve treatments and meet a growing unmet medical need.

The company said that the Cooperative Research Centre for Cell Therapy Manufacturing was developing an active wound care dressing for the treatment of diabetic wounds, consisting of a polymer-coated silicone dressing seeded with MSCs or similar cells.

The Centre's executive chair Dr Leanna Read said that rapid wound closure "reduces the risk of infection and wound management costs and improves health outcomes for patients".

"Our studies show that delivery of Cymerus MSCs via ... [our] polymer-coated dressing can accelerate re-epithelialisation and wound closure when compared to the dressing alone or treatment with commercially produced bone marrow-derived MSCs," Dr Read said. "We need only a small number of MSCs to seed the dressing, so we expect that this product could be produced at a low cost and positioned very competitively against existing treatment options."

Cynata said that the Centre evaluated cells from five different sources: Cymerus MSCs, bone marrow-derived MSCs supplied by a commercial manufacturer, and MSCs derived from dental pulp, bone chips and gingival fibroblasts from the gums that were supplied by an academic collaborator.

The company said that the primary outcome was the extent of re-epithelialisation, or skin restoration, of the wound surface after three days, which was representative of the speed of wound healing.

Cynata said that dressings seeded with MSCs from any source were found to be more effective than the dressing alone, but dressings seeded with its Cymerus MSCs "resulted in significantly greater re-epithelialisation after three days, 86 percent, than dressings seeded with commercially available bone marrow-derived MSCs, 51 percent, with MSCs derived from dental pulp, gingival fibroblasts and bone chips resulted in re-epithelialisation of 68, 80 and 91 percent, respectively, after three days.

The company said that the results suggested that the most effective cell types were Cymerus MSCs or MSCs derived from gingival fibroblasts or bone chips, but, the gingival fibroblast and bone chip-derived MSCs were produced in an academic laboratory under non-good manufacturing practice conditions and there were "major challenges associated with producing clinical-grade cells from those sources at commercial scale".

Cynata said that its Cymerus technology platform provided a readily available and effectively limitless source of consistent, clinical-grade MSCs.

Cynata head of product development Dr Kilian Kelly said the company was "very encouraged by these results and believe the combination of [the] CRC's wound-dressing technology with Cynata's Cymerus MSCs has the potential to address a huge and growing unmet medical need".

Cynata was up 2.5 cents or 1.9 percent to \$1.33.

BENITEC BIOPHARMA

Benitec says its one-for-two rights offer has raised \$6,195,254 of a hoped-for \$17,437,203, taking the total raised with the previous placement to \$8.8 million.

Benitec said it that 35,758,638 shares were taken up under the offer at 17 cents a share with a further 684,033 shares taken in the over-subscription facility, leaving a non-underwritten shortfall of 66,129,112 shares.

The company said the funds would be used for its phase II clinical trial of its head and neck squamous cell carcinoma program, the progression of its oculo-pharyngeal muscular dystrophy (OPMD) program to the clinic in early 2019, and with the development of its earlier stage technologies (BD: Apr 30, 2018).

Benitec was unchanged at 16.5 cents.

OPTISCAN IMAGING

Optiscan says its Convivo confocal microscope has European approval, there have been delivery delays and interim executive chairman Darren Lurie will be paid \$1,000 a day.

Optiscan said that Carl Zeiss Meditec AG had received Conformité Européenne (CE) mark approval for the Zeiss Convivo confocal microscope, and deliveries of the microscopes planned for January and March 2018 had taken place, with deliveries planned for June 2018 expected to be dispatched from July.

The company said that chairman Darren Lurie had been appointed as interim executive chairman on \$1,000 a day in addition to his non-executive chairman's fees.

Optiscan fell 0.1 cents or 1.5 percent to 6.5 cents.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says that 25.44 percent of its investors at its annual general meeting opposed the remuneration report, providing a first strike.

The TPI meeting results notice said that 27,621,476 votes (74.56%) supported the report with 9,423,732 votes (24.44%) against.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed by more than 50 percent of votes the directors must stand for re-election at a subsequent meeting within 90 days.

The company said that the employee share plan faced 3.56 percent opposition with the ratification of a placement and the re-election of director Stuart Black supported by more than 99 percent of votes.

TPI's most recent Appendix 3B new issue announcement said it had 81,085,594 shares on issue, meaning that the votes against the remuneration report amounted to 11.6 percent of the company, sufficient to requisition extraordinary general meetings.

TPI was unchanged at \$1.42.

ONCOSIL MEDICAL

Oncosil has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 34.5 percent from 14.5 cents on May 23 to 19.5 cents on May 31, 2018 and noted a significant increase in trading volume.

Oncosil was unchanged at 19 cents with 2.05 million shares traded.

MMJ PHYTOTECH

MMJ says it has invested \$C700,000 (\$A716,061) for a 12.7 percent shareholding in the Bien Ventures for marijuana extract powders for food and drink.

MMJ said that it bought 2.8 million shares at 25 Canadian cents a share, with each share having an attaching warrant exercisable at 35 Canadian cents within 36 months.

The company said that the Calgary, Alberta-based Bien Ventures was “an intellectual property, branding and licencing company ... focused on exploiting the intellectual property for its formulation and brand of soluble, odorless and flavorless micro-dosed [cannabidiol and tetrahydrocannabinol] powders that can be added to any beverage or food by a consumer”.

MMJ said that the final testing of Bien’s formulation was underway and on completion, the initial launch market would be California, with distribution to between 30 and 50 dispensaries expected to begin by the end of this year.

The company said that Bien’s business model “precludes handling the cannabis plant and/or seeking state licensing, to avoid status as a cannabis company”.

MMJ was up half a cent or 1.6 percent to 31 cents.

RHINOMED

Paul and Eleanor Stephens say they have increased their holding in Rhinomed from 8,036,759 shares (6.83%) to 9,351,129 shares (7.95%).

The substantial shareholder notice said that the San Francisco-based Stephens acquired the 1,314,370 shares between May 2 and 30, 2018 for \$US117,654 (about \$A155,871) or 11.9 cents a share.

Rhinomed was untraded at 12 cents.

MEMPHASYS

Robert Peters and Peters Investments say they have become substantial shareholders in Memphasys with 650,000,000 shares or 12.723 percent.

Mr Peters said that he acquired the shares on May 25, 2018 at 0.1 cents a share.

Memphasys fell 0.1 cents or 50 percent to 0.1 cents.

IMAGION BIOSYSTEMS

Imagion says it will release 3,483,333 shares from ASX escrow on June 15, 2018.

Imagion’s most recent Appendix 3B new share issue announcement said it had 91,232,785 shares quoted on the ASX, and following the release of the 3,483,333 shares on June 15, would have a further 109,050,045 shares remaining in ASX escrow along with 15,550,000 performance rights.

Imagion fell 0.1 cents or 1.6 percent to 6.2 cents.

BTC HEALTH (FORMERLY BIOTECH CAPITAL)

BTC says that director Bruce Hancox has retired, effective from May 31, 2018.

BTC executive chairman Dr Richard Treagus said the Mr Hancox had “provided valuable support, insight and expertise to the BTC Health board since 2015 always remaining highly engaged and generous with his time”.

BTC was unchanged at 18.5 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT MAY 31, 2018

Company \$Am	Jun-17	May-18	Jun-18
Cochlear	8,418	11,168	11,288
CSL	58,725	77,071	84,079
Resmed	13,342	18,119	19,296
BDI-20			
Bionomics	173	280	282
Clinuvel	326	561	580
Compumedics	68	68	128
Cyclopharm	56	74	69
Ellex	121	90	82
Impedimed	227	212	200
Medical Developments	278	409	346
Mesoblast	903	693	725
Nanosonics	840	721	796
Neuren	116	303	307
Opthea	160	100	91
Pharmaxis	85	101	99
Polynovo	124	340	401
Immutep (Prima)	64	73	112
Pro Medicus	534	827	765
Reva	377	157	114
Sirtex	692	1,552	1,640
Telix	21	124	136
Viralytics	265	479	484
Volpara	41	97	140
Second 20			
Actinogen	43	32	46
Admedus	71	97	82
Airxpanders	228	42	24
Avita	49	59	53
Benitec	31	38	36
Cynata	52	116	119
Dimerix	15	16	14
Factor Therapeutics	46	33	41
Genetic Signatures	41	33	41
ITL Health	52	22	21
LBT Innovations	34	28	23
Oncosil	54	80	119
Optiscan	36	30	28
Orthocell	27	26	30
Osprey	93	53	53
Prescient	12	21	29
Prana	25	22	25
Starpharma	243	441	437
Universal Biosensors	63	39	41
Uscom	21	28	24

* Biotech Daily editor, David Langsam, owns shares in Acrux, Benitec, Innate, Mesoblast, Nanosonics, Patrys, Polynovo, Telix, Volpara and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in a range of other biotechnology companies: <http://www.australianethical.com.au/who-we-invest-in>. These holdings are liable to change.

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